K050734

JUN 3 - 2005

510(k) Summary
(As required by 21 CFR 807.92(a))

A. Submitter Information	Bioject Medical Technologies, Inc. 20245 S.W. 95th Ave. Tualatin, OR 97062 Phone: 800-683-7221, ext. 4144 Fax: 503-692-6698 Email: MTalbert@bioject.com Contact: Melanie Talbert Director Product Development Date: March 18, 2005
B. Device Information Trade/Proprietary Name:	cool.click®
Common Name:	Needle-Free Jet Injector
Classification Name:	Jet Injector, Non-Electrically Powered Fluid Injector
Predicate Device(s):	Clicker™ (cool.click®) K994384
Device Description:	Needle-Free Self Injection Device for Personal Use with Saizen® [somatropin (rDNA origin) for injection]. Needle-Free Injector, Jet Injector
Intended Use:	Needle-Free Self Injection Device for Personal Use with Saizen® [somatropin (rDNA origin) for injection].
C. Comparison of Required Technological Characteristics:	This submission changes the labeling of the cool.click® to expand the indications for use to include adults in accordance with changes approved for Saizen® indications. There are no significant changes in the device design or function.

D. Summary and Conclusion of Nonclinical and Clinical Tests:	No new nonclinical or clinical tests were conducted as part of this submission. Non clinical and clinical studies with Saizen® were conducted for the predicate cool.click submission K994384. The predicate submission included Saizen® pharmacokinetic and pharmacodynamic studies using the cool.click injector in adults demonstrating bioequivalence between needle and needle-free delivery of growth hormone.

Summary:

This submission describes the labeling changes associated with the changes to indications for use for the cool.click® Needle-Free Self Injection Device for Personal Use with Saizen®. Previously submitted nonclinical and clinical studies have demonstrated the bioequivalence between needle and cool.click® needle-free delivery of growth hormone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

Susan Frank, J.D.
Director, Regulatory Affairs
Bioject Medical Technologies, Incorporated
20245 S.W. 95th Avenue
Tualatin, Oregon 97062

Re: K050734
Trade/Device Name: cool.click®
Regulation Number: 21 CFR 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: March 18, 2005
Received: March 21, 2005

Dear Ms. Frank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K050734

Device Name: cool.click®

Indications For Use: This product is indicated for Needle-Free Self Injection of Saizen® [somatotropin (rDNA origin) for the replacement of endogenous growth hormone in adults with growth hormone deficiency.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K050734